

REMARKS

Claims 1-20 have been canceled without prejudice. New claims 21-27 have been presented herein. These claims are believed to place this application in condition. Support for the Markush group of organic acids is found in the as-filed Specification at page 9, lines 15-18. Support for particular concentrations of organic acids is found at page 9, line 20 through page 10, line 5, and at page 12, lines 19-22. Support for concentrations of nitrite is found at page 10, lines 6-11, in the table on page 21, and at page 23, lines 16-17. Accordingly, none of the amendments made herein constitutes the addition of new matter.

The Effective Filing Date of Claims 1, 19 and 20

The Patent Office has noted that the previously amended subject matter does not explicitly provide descriptive support from a prior application, but that claims 1 and 19 are entitled to effective filing dates of 2/21/94 and that claim 20 is entitled to an effective filing date of 6/11/99.

The Rejection under 35 U.S.C. 112, first paragraph

Claim 20 has been rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

In the interest of advancing prosecution and without acquiescing to the rejection, new independent claim 21 does not recite that the pH is sufficiently high to potentiate the patient's immune system selectively against infection (as compared to normal cells); thus the rejection for lack of written description no longer applies and should be withdrawn.

The Rejection under 35 U.S.C. 112, second paragraph

Claim 1 has been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully traverse this rejection.

Claim 1 was said to be confusing as to whether the acidifying agent was responsible for the pH at the environment of use.

The new base claim now recites **said organic acid is sufficient to generate a pH at the environment of use below pH 4**". We believe that this language should overcome the concerns of the Examiner about environmental pH. Accordingly, the withdrawal of the rejection is respectfully requested.

The Rejection under 35 U.S.C. 102

Claims 1 and 19 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by Biosis Abstract 1987:466265. Applicants respectfully traverse this rejection.

The cited abstract is said to disclose topical staining with silver nitrate followed by application of 5% or 10% salicylic acid in petrolatum, and the Patent Office has taken the position that dosage forms are necessarily disclosed in that piece of prior art. It has been alleged that "applicant's dosage form does not require any specificity as to how the acid and the nitrate components are physically connected relative to each other within the dosage form and that it seems that the reference discloses those ingredients to be separately help prior to their final admixture and also that the 5% or 10% salicylic acid necessarily would provide the pH less than 4. The Patent Office further alleged that the release of NO or NO₂ would result from the application of the salicylic acid over the silver nitrate.

Applicants respectfully point out that the present claims are directed to separate compositions for admixture at the environment of use. The instant claims specify that the organic acid is sufficient to produce a pH of less than 4 at the environment of use

and that NO or NO₂ are generated at the environment of use. The cited reference relates to compositions applied to an environment of use several hours apart, and these particular effects are not recited. Thus each limitation of the instant claims are not embodied in the teachings of the cited reference. In fact, the reference teaches salicylic acid alone as the material for treatment, and the silver nitrate is merely a material for visualizing tissue condition; thus it is not an essential feature of any dosage form taught by the abstract. Moreover, the present claims as amended do not recite nitrate in either component of the dosage form.

Applicants maintain that the present claims are not anticipated by the cited reference, and the withdrawal of the rejection is respectfully requested.

Claims 1 and 19 have been rejected as allegedly anticipated by Mardi et al. (US 4,595,591). Applicants respectfully traverse this rejection.

The Patent Office has stated that the cited Mardi patent discloses a composition in the form of two vials, one containing a sodium nitrite solution and the other containing nitric acid in a concentration an amount with a combined pH of below about 1 and organic acids. The Mardi composition is used to treat verruca vulgaris and condyloma acuminatum, which are both conditions caused by papillomavirus. Prior arguments related to lack of mummification of tissue have not been found persuasive.

In the interest of advancing prosecution and without acquiescing to the rejection, claims 1 and 19 have been canceled without prejudice. New claim 21 recites that the acidifying agent consists of an organic acid, and that it is sufficient to produce a pH of less than 4 at the environment of use. This precludes nitric acid contributing to the pH at the environment of use, as appears to be the case in Mardi.

In view of the foregoing, Applicants respectfully maintain that the present invention as claimed is not anticipated by the Mardi reference, and the withdrawal of the rejection is respectfully requested.

Conclusion

Applicants respectfully submit that the pending claims are in condition for allowance and early notification thereof is requested.

If, in the interest of expediting prosecution, the Examiner has questions or comments, he is invited to telephone the undersigned at the indicated telephone number.

This Response is accompanied by a Revocation of Power of Attorney and

- Appointment of New Agent, Information Disclosure Statement, Petition for Extension of Time (two months), Request for Continued Examination and payment of the necessary fees: \$225 as required by 37 C.F.R. 1.16 and \$395 as required by 37 C.F.R. 1.17(e). It is believed that this Amendment and accompanying documents does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any fees due pursuant to the foregoing Rules to Deposit Account No. 07-1969.

Respectfully submitted,



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